DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

939620

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

April 15, 2003

WARNING LETTER
CHI-12-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Pedro V. Segura, President
Prime Dental Manufacturing, Inc.
3735 W. Belmont Ave.
Chicago, IL 60618

Dear Mr. Segura:

During the inspection of your firm from February 20 to February 21, 2003, Investigator Karen E. Masley determined that your firm manufactures restorative dental composites. Restorative dental composites are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish quality system procedures and instructions. 21 CFR § 820.5.

2. Failure to establish and maintain procedures for implementing corrective and preventive action. 21 CFR § 820.100(a).

3. Failure to establish and maintain complaint-handling procedures for receiving, reviewing, and evaluating complaints. 21 § CFR 820.198(a).

4. The Device Master Record does not include or refer to the location of device specifications. For example, your firm failed to document finished device specifications for the Visible Light Cure Composite and the Chemical Cure Composite. 21 CFR § 820.181.

5. Failure to establish and maintain procedures for acceptance or rejection of finished device production runs, lots, or batches. For example, finished product testing for the Visible Light Cure Composite was not documented. Your firm started production of this product in January 2000. 21 CFR § 820.80(d)

6. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate, verification, review, and approval of design changes before their implementation. 21 CFR § 820.30(i).

7. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. 21 CFR § 820.22.

8. Failure to document training. For example, your firm did not document process-specific training for production employees. 21 CFR § 820.25(b).

9. Failure to establish and maintain Medical Device Reporting procedures. 21 CFR § 820.198(d).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director